

Accordingly, adequate correction has been made to the specification and any objections should be removed.

#### *Objection to the Claims*

Examiner has objected to claims 1, 3-17, 54 and 59.

Applicants respectfully disagree with Examiner's objection that the term "position" should be replaced with the term "residue." As used in claim 10, "residue" refers to any one of the 20 amino acids. Whereas, throughout the claims, "position" refers to the location of the a specific amino acid residue in a sequence, e.g. in SEQ ID NO:2. Thus, the two terms are not interchangeable and applicants respectfully request removal of the objection.

Applicants have amended claim 1 to spell out FVII and FVIIa.

Applicants have amended claim 1 to insert "SEQ ID NO:2" as suggested by Examiner.

Applicants thank Examiner for pointing out error in claim 11. Claim 11 has been amended as suggested by Examiner.

#### *Sequence Compliance*

Applicants herewith submit a substitute copy of the Sequence Listing in both paper and electronic format. The Sequence Listing has been amended to provide SEQ ID NOs to amino acid sequences on page 15, lines 26-27 as pointed out by Examiner. Applicants certify that the information provided in paper format is identical to the information provided in electronic format.

#### *Claim Rejections - §112, Second paragraph*

Examiner has rejected claims 1, 3-17, 54 and 59 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, with regard to claim 1 and its dependent claims, Examiner has argued that the instant claims do not set forth a SEQ ID NO: for hFVII and SEQ ID NO:2 only applies to hFVIIa. Applicants would like to point out that SEQ ID NO:2 refers to both hFVII and hFVIIa. While a proteolytic cleavage occurs to form hFVIIa, a disulfide bridge links the two resulting chains. It is generally accepted that because no loss of amino acid residues occurs and the resulting chains remain bound to one another, the sequence for hFVII and hFVIIa are the same, which in this case is provided in SEQ ID NO:2.

With regard to claim 4, upon entry of the amendment to claim 1, the rejection is moot.

With regard claim 10, please see page 9 of the Specification which describes the terminology. Specifically, page 9, line 15 provides “[i]nsertion of an additional amino acid residue, such as insertion of an alanine residue after G124 is indicated by G124GA. Insertion of two additional alanine residues after G124 is indicated by G124GAA, etc.”

With regard to claim 17, claim 17 has been canceled and thus the rejection is moot.

Accordingly, Applicants respectfully request removal of the claim rejections based on 35 U.S.C. 112, second paragraph.

***Claim Rejections - §102***

Examiner has rejected claims 1, 14, 15, 17 and 54 under 35 U.S.C. 102 as being anticipated by Hu et al. Examiner has also rejected claims 1, 3, 14-17, 54 and 59 under 35 U.S.C. 102 as being anticipated by Nicolaisen et al. Examiner has also rejected claims 1, 3-7, 14, 15, 17, 54 and 59 under 35 U.S.C. 102 as being anticipated by Andersen et al. Examiner has also rejected claims 1, 3, 14, 15, 17, 54 and 59 under 35 U.S.C. 102 as being anticipated by Ruf et al.

Applicants have amended claim 1 and upon entry the aforementioned rejections are overcome. As amended, claim 1 provides that the FVII or FVIIa variant comprises the substitution D196K which is not disclosed in the above references. Accordingly, Applicants respectfully request removal of the claim rejections based on 35 U.S.C. 102.

### **Conclusion**

For the foregoing reasons, Applicants submit that the claims are in condition for allowance and Applicants respectfully request reexamination of the present application, reconsideration and withdrawal of the present rejections and objections, and entry of the amendments. Should there be any further matter requiring consideration, Examiner Liu is invited to contact the undersigned counsel.

If there are any fees due in connection with the filing of the present response, please charge the fees to undersigned's Deposit Account No. 03-4000. If a fee is required for an extension of time not accounted for, such an extension is requested and the fee should also be charged to undersigned's deposit account.

Date: December 21, 2009

Bayer HealthCare LLC  
800 Dwight Way  
Berkeley, CA 94710  
Telephone: (510) 669-4603  
Fax: (510) 705-7904

Respectfully submitted,

/ Fernando Santos, Reg. No. 57,822 /

---

Fernando Santos  
Reg. No. 57,822  
Attorney for Applicants